Attorney Docket No. 109536-117

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): **Araki et al.**	)	Examiner:
Reissue of U.S. Patent No.: **5,945,420**	)	Group Art Unit:
Originally Issued: **August 31, 1999**	)	
For: **IMMUNOPOTENTIATING AND INFECTION PROTECTIVE AGENT AND PRODUCTION THEREOF**	)	

I HEREBY CERTIFY THAT THE ATTACHED PAPERS AND FEES ARE BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 C.F.R. §1.10 ON THE DATE INDICATED BELOW ADDRESSED TO: BOX REISSUE, ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231 ON

DATE: AUGUST 30, 2001

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Assistant Commissioner of Patents
Washington, D.C. 20231
ATTN: BOX REISSUE

PRELIMINARY AMENDMENT UNDER 37 C.F.R. §1.173(B)(2)

Dear Sir:

In the above-referenced Reissue Application, please make the following amendments.

AMENDMENTS

In the claims:

Please add the following new claims:

9. A method for treating infection by administering to a patient in need of such treatment a composition comprising riboflavin and/or riboflavin derivative.

10. The method according to claim 9 wherein riboflavin and/or riboflavin derivative is the sole active ingredient of the composition.

11. The method according to claim 10 further comprising a patient with sepsis.

12. The method according to claim 9 wherein the riboflavin derivative is flavin mononucleotide, flavin adenine dinucleotide or a pharmacologically acceptable salt of riboflavin.

13. The method according to claim 9 wherein the composition is administered to the patient in an amount ranging from 0.1 to 500 mg/kg of weight of the patient.

14. The method according to claim 9 wherein the composition is administered to the patient in a form of intramuscular injection, intravenous injection, subcutaneous injection or oral administration.

15. The method according to claim 9 further comprising a water-soluble polymer or lecithin.

16. The method according to claim 15 wherein the water-soluble polymer is one or more selected from the group consisting of polyvinyl pyrrolidone, sodium carboxymethyl cellulose, methy cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, sodium chondroitin sulfate, polyethylene-hardened caster oil, polyoxysorbitan fatty acid esters and polyvinyl alcohol.

17. The method according to claim 16 wherein the lecithin is one or more selected from the group consisting of yolk lecithin, soybean lecithin and hydrogenated lecithins thereof.

18. The method according to claim 9 further comprising an antibiotic.

19. A method of treating a patient with an infection comprising administering a composition comprising riboflavin and/or riboflavin derivative in an amount sufficient to enhance the immune function of the patient.

20. The method according to claim 19 wherein riboflavin and/or riboflavin derivative is the sole active ingredient of the composition.

21. The method according to claim 20 further comprising a patient with sepsis.

22. The method according to claim 19 wherein the riboflavin derivative is flavin mononucleotide, flavin adenine dinucleotide or a pharmacologically acceptable salt of riboflavin.

23. The method according to claim 19 wherein the composition is administered to the patient in an amount ranging from 0.1 to 500 mg/kg of weight of the patient.

24. The method according to claim 19 wherein the composition is administered to the patient in a form of intramuscular injection, intravenous injection, subcutaneous injection or oral administration.

25. The method according to claim 19 further comprising a water-soluble polymer or lecithin.

26. The method according to claim 25 wherein the water-soluble polymer is one or more selected from the group consisting of polyvinyl pyrrolidone, sodium carboxymethyl cellulose, methy cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, sodium chondroitin sulfate, polyethylene-hardened caster oil, polyoxysorbitan fatty acid esters and polyvinyl alcohol.

27. The method according to claim 26 wherein the lecithin is one or more selected from the group consisting of yolk lecithin, soybean lecithin and hydrogenated lecithins thereof.

28. The method according to claim 19 further comprising an antibiotic.

29. A method of enhancing the immune response of a patient with an infection by administering to the patient a composition comprising riboflavin and/or riboflavin derivative.

30. The method according to claim 29 wherein riboflavin and/or riboflavin derivative is the sole active ingredient of the composition.

31. The method according to claim 30 further comprising administering a sufficient amount of riboflavin and/or riboflavin derivative to a patient with sepsis.

32. The method according to claim 29 wherein the riboflavin derivative is flavin mononucleotide, flavin adenine dinucleotide or a pharmacologically acceptable salt of riboflavin.

33. The method according to claim 29 wherein the composition is administered to the patient in an amount ranging from 0.1 to 500 mg/kg of weight of the patient.

34. The method according to claim 29 wherein the composition is administered to the patient in a form of intramuscular injection, intravenous injection, subcutaneous injection or oral administration.

35. The method according to claim 29 further comprising a water-soluble polymer or lecithin.

36. The method according to claim 35 wherein the water-soluble polymer is one or more selected from the group consisting of polyvinyl pyrrolidone, sodium carboxymethyl cellulose, methy cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, sodium chondroitin sulfate, polyethylene-hardened caster oil, polyoxysorbitan fatty acid esters and polyvinyl alcohol.

37. The method according to claim 36 wherein the lecithin is one or more selected from the group consisting of yolk lecithin, soybean lecithin and hydrogenated lecithins thereof.

38. The method according to claim 29 further comprising an antibiotic.

39. A method for treating a patient with sepsis by administering to such a patient a sufficient amount of a composition comprising riboflavin and/or riboflavin derivative.

40. The method according to claim 39 wherein riboflavin and/or riboflavin derivative is the sole active ingredient of the composition.

41. The method according to claim 40 wherein the riboflavin derivative is flavin mononucleotide, flavin adenine dinucleotide or a pharmacologically acceptable salt of riboflavin.

42. The method according to claim 39 wherein the composition is administered to the patient in an amount ranging from 0.1 to 500 mg/kg of weight of the patient.

43. The method according to claim 39 wherein the composition is administered to the patient in a form of intramuscular injection, intravenous injection, subcutaneous injection or oral administration.

44. The method according to claim 39 further comprising a water-soluble polymer or lecithin.

45. The method according to claim 44 wherein the water-soluble polymer is one or more selected from the group consisting of polyvinyl pyrrolidone, sodium carboxymethyl cellulose, methy cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, sodium chondroitin sulfate, polyethylene-hardened caster oil, polyoxysorbitan fatty acid esters and polyvinyl alcohol.

46. The method according to claim 45 wherein the lecithin is one or more selected from the group consisting of yolk lecithin, soybean lecithin and hydrogenated lecithins thereof.

47. The method according to claim 39 further comprising an antibiotic.

48. A method of treating a patient with sepsis comprising administering a composition comprising riboflavin and/or riboflavin derivative in an amount sufficient to enhance the immune function of the patient, wherein riboflavin and/or riboflavin derivative is the sole active ingredient.

49. The method according to claim 48 wherein the riboflavin derivative is flavin mononucleotide, flavin adenine dinucleotide or a pharmacologically acceptable salt of riboflavin.

50. The method according to claim 48 wherein the composition is administered to the patient in an amount ranging from 0.1 to 500 mg/kg of weight of the patient.

51. The method according to claim 48 wherein the composition is administered to the patient in a form of intramuscular injection, intravenous injection, subcutaneous injection or oral administration.

52. A method of treating a patient with sepsis comprising administering a composition comprising riboflavin monophosphate in an amount sufficient to enhance the immune function of the patient, wherein riboflavin monophosphate is the sole active ingredient.

53. The method according to claim 52 wherein the composition is administered to the patient in an amount ranging from 0.1 to 500 mg/kg of weight of the patient.

54. The method according to claim 52 wherein the composition is administered to the patient in a form of intramuscular injection, intravenous injection, subcutaneous injection or oral administration.

REMARKS

Claims 1-54 are pending.

Claims 1-8 issued in U.S. Patent No. 5,945,420. Claims 9-54 have been added in this preliminary amendment.

Claim 9 has been added to cover a method for treating infection by administrating to a patient in need of such treatment a composition comprising riboflavin and/or riboflavin derivative. Claims 10-18 have been added to cover specific embodiments of the method of treatment of claim 9. Support for these new claims can be found in the specification, for example, at column 2, lines 15-20 and lines 35-59; column 3, lines 23-56; column 4, lines 3-5, lines 28-39 and lines 52-66; column 5, lines 20-27; column 6, lines 8-13; and Tables 1-6 of the issued patent.

Claim 19 has been added to cover a method for treating infection by enhancing the immune function of a patient by administering to the patient a composition comprising riboflavin and/or riboflavin derivative. Claims 20-28 have been added to cover specific embodiments of the method of enhancing the immune function of claim 19. Support for these new claims can be found in the specification, for example, at column 2, lines 15-20 and lines 35-59; column 3, lines 17-56; column 4, lines 3-5, lines 28-39 and lines 52-66; column 5, lines 20-27; column 6, lines 8-13; and Tables 1-6 of the issued patent.

Claim 29 has been added to cover a method for enhancing the immune response of a host with an infection by administering to the host a composition comprising riboflavin and/or riboflavin derivative. Claims 30-38 have been added to cover specific embodiments of the method of enhancing the immune function of claim 29. Support for these new claims can be found in the specification, for example, at column 2, lines 15-20 and lines 35-59; column 3, lines 17-56; column 4, lines 3-5, lines 28-39 and lines 52-66; column 5, lines 20-27; column 6, lines 8-13; and Tables 1-6 of the issued patent.

Claim 39 has been added to cover a method of treating a patient with sepsis by administering to such a patient a sufficient amount of a composition comprising riboflavin and/or riboflavin derivative. Claims 40-47 have been added to cover specific embodiments of the method of enhancing the immune function of claim 39. Support for these new claims can be found in the specification, for example, at column 2, lines 15-20 and lines 35-59; column 3, lines 17-56; column 4, lines 3-5, lines 28-39 and lines 52-66; column 5, lines 20-27; column 6, lines 8-13; and Tables 1-6 of the issued patent.

Claim 48 has been added to cover a method of treating a patient with sepsis by administering to such a patient a composition comprising riboflavin and/or riboflavin derivative in an amount sufficient to enhance the immune function of the patient wherein riboflavin and/or riboflavin derivative is the sole active ingredient. Claims 49-51 have been added to cover specific embodiments of the method of enhancing the immune function of claim 48. Support for these new claims can be found in the specification, for example, at column 2, lines 57-59; column 3, lines 17-56; column 4, lines 52-56; column 5, lines 20-27; column 6, lines 8-13; and Tables 1 and 4 of the issued patent.

Claim 52 has been added to cover a method of treating a patient with sepsis by administering to such a patient a composition comprising riboflavin monophosphate in an amount sufficient to enhance the immune function of the patient wherein riboflavin monophosphate is the sole active ingredient. Claims 53 and 54 have been added to cover specific embodiments of the method of enhancing the immune function of claim 52. Support for these new claims can be found in the specification, for example, at column 3, lines 25-31 and lines 45-57; column 4, lines 52-56; column 5, lines 20-27; column 6, lines 8-13; and Tables 1 and 4-7 of the issued patent.

None of the above new claims adds any new matter.

CONCLUSION

Applicant encloses herewith a reissue application fee transmittal form indicating the fee to be paid for this Application.

No additional fees are believed to be due in connection with this communication. However, please apply any additional charges, or credit any overpayment, to our Deposit Account No. 08-0219.

Respectfully submitted,

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